UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Latham Sean Bean, individually and as Personal Representative of the Estate of Hubert E. Bean, Jr., deceased, Plaintiff, v. Upsher-Smith Pharmaceuticals, Inc. and Taro Pharmaceuticals USA, Inc., Defendants.	)	Civil Action No.: 4:16-cv-01696-RBH **ORDER**

This matter is before the Court on Defendant Upsher-Smith Pharmaceuticals, Inc.'s [ECF No. 19] motion to dismiss and Taro Pharmaceuticals USA, Inc.'s [ECF No. 22] motion to dismiss. For the reasons stated below, the Court grants the motions to dismiss.[1]

Factual[2] and Procedural Background

Plaintiff filed his Complaint on May 26, 2016, alleging claims against Defendants Upsher-Smith Pharmaceuticals, Inc. ("Upsher-Smith") and Taro Pharmaceuticals USA, Inc. ("Taro") for: 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; 4) negligence per se - "off label" marketing/sale and failure to provide Medication Guide; 5) fraud and deceit; and 6) wrongful death. The claims arise from Hubert E.

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[1] Under Local Civil Rule 7.08 (D.S.C.), "hearings on motions may be ordered by the Court in its discretion. Unless so ordered, motions may be determined without a hearing." Upon review of the briefs, the Court finds that a hearing is not necessary.

[2] When reviewing a motion made under Federal Rule of Civil Procedure 12(b)(6), the court must "accept all well-pleaded allegations in the plaintiff's complaint as true and draw all reasonable factual inferences from those facts in the plaintiff's favor." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999). Accordingly, the Court will assume the facts alleged in the Complaint are true for purposes of resolving the pending motion to dismiss.

Bean, Jr.'s use of the pharmaceutical drug amiodarone for treatment of his non-life threatening atrial fibrillation. Plaintiff alleges that after ingesting amiodarone manufactured by Upsher-Smith and Taro, Hubert Bean developed pulmonary fibrosis, which eventually led to his death. [Complaint, ECF No. 1 at ¶ 2]. The amiodarone tablets were manufactured and sold as a generic version of Wyeth's Cordarone®.

The FDA approved Cordarone® (amiodarone hydrochloride) only as a drug of "last resort" for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Plaintiff alleges Wyeth aggressively and successfully marketed Cordarone® for inappropriate "off label" uses as a "first line anti-arrhythmic therapy." *Id*. at ¶ 30. Generally, Plaintiff alleges Hubert Bean was not in a situation of last resort as to the management of his atrial fibrillation. *Id*. at ¶ 34.

Plaintiff alleges that as a result of Wyeth's off-label promotion, amiodarone became a first line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug. *Id*. at ¶ 31. Wyeth's alleged fraudulent and misleading marketing campaigns resulted in warning letters from the FDA to stop the false and misleading promotion of the drug that downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy. *Id*. The FDA letters noted it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. *Id*. Unapproved uses are deemed "off-label" because they have not been approved by the FDA. *Id*.

In 1998, Wyeth received approval for the manufacture, marketing, sale and distribution of the generic formulation of Cordarone®, amiodarone hydrochloride. *Id*. at 32. Plaintiff asserts

Defendants Upsher-Smith and Taro took advantage of the pervasive promotional activities of Wyeth and allege that Defendants' version of the drug directly benefitted from Wyeth's marketing of the drug for "off-label" uses. *Id*.

Plaintiff alleges Defendants were required to provide patients prescribed amiodarone with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Wyeth. *Id*. at ¶ 33. The Medication Guide for amiodarone outlined serious side effects, such as lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. *Id*. at ¶ 39.

Beginning in October of 2013 and continuing through April of 2014, Bean was prescribed a course of 200 mg amiodarone tablets for treatment of his non-life threatening atrial fibrillation. *Id*. at ¶ 35. Bean was not aware that his use of amiodarone was for an "off-label" use and he did not receive the required Medication Guide from Defendants. *Id*. Correction of atrial fibrillation and any use except in situations of last resort were never FDA approved uses of Cordarone® or its generic equivalents. *Id*. Bean's prescription was for an "off-label" use and without the benefit of the FDA mandated Medication Guide. *Id*.

The prescriptions for the amiodarone tablets were marked with the numbers 51672-4025-04 and 00245-0147-60 and were manufactured by Taro and Upsher-Smith. *Id*. at ¶ 36. Plaintiff alleges the "off-label" prescription and distribution of the drug to control non-life threatening atrial fibrillation, also a direct result of the long term promotional efforts of Defendants and without the required Medication Guide, was a producing and proximate cause of Bean's physical condition and injuries from amiodarone toxicity. *Id*. Plaintiff alleges that if Bean had received the Medication

Guide, he would have been aware of the serious lung related side effects and would not have taken amiodarone. *Id.* at ¶ 38.

In the winter and early spring of 2014, Bean began to experience many of the symptoms outlined in the Medication Guide including shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. *Id*. at ¶ 44. Bean's condition continued to deteriorate and in May of 2014, he was admitted to McLeod Regional Medical Center with severe shortness of breath. *Id*. at ¶ 46. In June of 2014, Bean was admitted to McLeod with shortness of breath and acute and chronic respiratory failure. *Id*. Bean died on June 20, 2014. *Id*.

Plaintiff alleges Defendants received direct notice of adverse events resulting from the use of amiodarone including pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure such as that experienced by Bean. *Id*. at ¶ 49. Plaintiff alleges Defendants failed to disclose to the FDA, healthcare professionals, consumers, or Bean information concerning the incidents and actual adverse events, injuries, and deaths suffered by amiodarone users. *Id*. at ¶ 53.

Plaintiff alleges Defendants took advantage of the promotional efforts of Wyeth for "off-label" uses, in addition to their own efforts, including the following:

a) Direct-to-physician and direct-to-pharmacist promotion through sales representatives;

b) Promotion through funding and manipulation of so-called "educators" who organize and arrange continuing medical education (CME) courses for

physicians and pharmacists;

c) Formulation of unlawful conspiracies with certain medical marketing and medical “education” entities to promote – without appearing to promote – “off-label” uses;

d) Sponsorship and funding of the production of CME materials;

e) Cultivation and development of so-called “opinion leaders” in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;

f) Sponsorship of journal supplements and symposia on “off-label” uses;

g) Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on MedLine, or medical library, search;

h) Media advertisements and brochures, some of which were disguised as “educational materials”;

i) Coordination of physician-to-physician interactions that are biased toward “off-label” usages;

j) Internet listings that omit important warnings and information; and

k) Various other forms of marketing and promotion.

Id. at ¶ 53.

Plaintiff alleges the amiodarone manufactured and/or supplied by Defendants was not accompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such side effects. *Id*. at ¶ 58. Plaintiff claims the warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. *Id*.

Plaintiff further alleges the amiodarone manufactured, distributed, and/or supplied by Defendants was defective due to inadequate postmarketing warning and instruction because, after Defendants knew or should have known of the risk of injury from amiodarone, especially in "off-label" use, Defendants failed to provide adequate warnings to physicians and consumers, including Bean, and continued to aggressively sell amiodarone for "off-label" use. *Id*. at ¶ 61.

Plaintiff contends the warnings for amiodarone were vague, incomplete, and/or otherwise wholly inadequate. *Id*. at ¶ 67. Plaintiff alleges Defendants owed a duty to engage in honest and non-deceptive practices; exercise due care under the circumstances; exercise due care in the design, manufacture, marketing, promotion, sale, and distribution of amiodarone; to provide a reasonably safe and non-defective drug; to provide adequate and appropriate warnings; to comply with federal guidelines; and/or to sell and distribute the drug in accordance with FDA restrictions. *Id*. at ¶ 69.

Plaintiff filed his Complaint on May 26, 2016, alleging claims for: 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; 4) negligence per se - "off label" marketing/sale and failure to provide Medication Guide; 5) fraud and deceit; and 6) wrongful death. Plaintiff seeks compensatory and exemplary damages, applicable interest, costs, attorney's fees and all such other relief the Court deems proper.

Rule 12(b)(6) Standard

When deciding a motion to dismiss made under Federal Rule of Civil Procedure 12(b)(6), the Court must accept all well-pled facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009). A complaint must state a "plausible claim for relief" to survive a 12(b)(6) motion to dismiss. *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The Court will not dismiss the plaintiff's complaint so long as he provides adequate detail about his claims to show he has a "more-than-conceivable chance of success on the merits." *Owens v. Baltimore City State's Attorneys Office*, 767 F.3d 379, 396 (4th Cir. 2014) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 563. A complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." Id. at 570. However, when a plaintiff's assertions "amount to nothing more than a 'formulaic recitation of the elements' " of a cause of action, the Court may deem such allegations conclusory and not entitled to an assumption of veracity. *Iqbal*, 556 U.S. at 681 (quoting Twombly, 550 U.S. at 555).

Discussion

Plaintiff's complaint alleges six causes of action: 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; 4) negligence per se - "off label" marketing/sale and failure to provide Medication Guide; 5) fraud and deceit; and 6) wrongful death. Generally, Plaintiff alleges that Defendants failed to warn patients regarding the risks of amiodarone, failed to provide the required Medication Guide, and engaged in improper "off-

label" promotion and sale of amiodarone as a first line therapy for atrial fibrillation. Defendants argue Plaintiff's claims are either preempted by federal law or barred by the learned intermediary doctrine. The Court agrees.

I. Federal Preemption

A. *Mensing* and *Bartlett* Preemption

Defendants argue Plaintiff's claims are preempted pursuant to the Supreme Court cases *PLIVA Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466, 2470, 186 L.Ed.2d 607 (2013). *Mensing* and *Bartlett* address the preemptive effect of the Food, Drug, and Cosmetic Act ("FDCA") on state tort laws as they apply to generic drug manufacturers.

Under the Hatch–Waxman amendments, codified at 21 U.S.C. § 355(j), the FDCA imposes substantially different requirements on producers of name brand drugs and producers of non-branded, or generic, counterparts. Manufacturers of generic medications gain authorization to market their products by demonstrating that those products are equivalent to the previously authorized name brand versions in a number of ways, including formulation and labeling. Generic drug manufacturers must maintain this equivalence to maintain authorization. *See* 21 U.S.C. § 355(j). In other words, the FDCA and its related regulations limit a generic drug manufacturer's ability to attach additional warnings to their drug. While original brand companies are free to unilaterally disseminate additional information about their drugs-including updated warnings and instructions for use – through direct correspondence to healthcare providers, generic drug companies may not. "Federal law ... demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Mensing*, 564 U.S. at 618. In fact, "changes unilaterally made to strengthen a generic drug's warning label would violate the [federal law]." *Id*. at 614.

In *Mensing*, the Supreme Court made clear that under § 355(j) generic drug manufacturers are not entitled to unilaterally change their labeling and therefore any state law tort premised on the failure of a generic to alter its labeling is preempted. *Id*. at 618. In *Bartlett*, the Supreme Court emphasized that generics are also not permitted to change the formulation of their products. 133 S.Ct. at 2471, 2475. Further, the Court rejected the argument that a generic drug manufacturer is required to leave the marketplace in order to avoid state law liability resulting from its inability to change either its labeling or formulation. *Id*. at 2477. Stated another way, courts may not avoid preempting a state law by imposing liability on a generic manufacturer for choosing to continue selling its product. *Mensing* and *Bartlett* establish that under the FDCA a generic drug manufacturer may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability for its failure to change its labeling, design, or formulation. *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014).

Defendants argue that because they are prohibited under the FDCA from altering or changing amiodarone's warning label, Plaintiff's claims that Defendants failed to adequately warn Bean about the risk of pulmonary toxicity and other lung problems are preempted by federal law.

Plaintiff responds that *Mensing* and *Bartlett* do not apply because their claims do not challenge the adequacy or "content" of the warning label, but rather challenge Defendants' alleged "off-label" marketing and alleged failure to provide a Medication Guide to Bean. However, throughout the complaint Plaintiff alleges the warnings for amiodarone were inadequate and that Defendants failed to warn Bean of the risks of taking amiodarone. *See, e.g.* [Complaint at ¶¶ 58, 61, 67, 92, 98, 99, 122, 124, 131]. Because Defendants could not have changed the content of the warning label or Medication Guide and could not have disseminated additional warnings regarding

"off-label" use without violating federal law, each of Plaintiff's claims premised on Defendants' alleged failure to warn is due to be dismissed as preempted.

In *Drager v. PLIVA USA, Inc.*, the plaintiff brought claims against PLIVA related to the marketing and sale of metoclopramide. *Drager*, 741 F.3d at 476. The complaint alleged claims under Maryland state law for negligent marketing, strict liability, breach of warranty, negligent misrepresentation, and fraudulent concealment. *Id*. at 476-79. The Fourth Circuit broadly interpreted *Mensing* and *Bartlett* to find each of plaintiff's causes of action preempted. The court held that "[because each alleged cause of action logically requires PLIVA to either change its labeling, change its design or formulation, exit the market, or accept state tort liability, the underlying Maryland laws as applicable here are preempted." *Id*. at 476. With respect to the negligent misrepresentation and fraudulent concealment claims, the court observed:

> Assuming that PLIVA's representations are false or misleading because its metoclopramide is unreasonably unsafe as marketed, it has no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or truthful. Therefore, PLIVA's only remaining options are to leave the market or accept tort liability. As a result, Gross's misrepresentation and fraudulent concealment claims are preempted by the FDCA.

Id. at 479.

Like the claims in *Drager*, Plaintiff's "off-label" promotion claims are due to be dismissed as preempted under *Mensing* and *Bartlett*. Plaintiff argues that his "off-label" promotion claims are not preempted under *Mensing* and *Bartlett* because the claims do not challenge the adequacy or content of the manufacturer's warning for amiodarone. The basis for Plaintiff's "off-label" marketing claim is that Defendants, by virtue of their marketing of amiodarone for first line non-life

threatening atrial fibrillation treatment instead of "last resort" treatment, rendered the manufacturer's warning inadequate. Defendants are prohibited by the FDCA and FDA regulations from adding or strengthening any warnings for amiodarone to address any risks associated with off-label use. If successful, Plaintiff's "off-label" promotion claims would necessarily require Defendants to either: 1) change the warning label or disseminate additional warnings to reflect the alleged additional dangers associated with the "off-label" use of amiodarone for atrial fibrillation; 2) accept state tort liability; or 3) exit the market place. As with the claims in *Drager*, such a result requires preemption under *Mensing* and *Bartlett*. Plaintiff's "off-label" promotion claims, whether sounding in fraud or negligence, are preempted by the FDCA.

Because each alleged cause of action requires Defendants to either change the labeling for amiodarone, change its design or formulation, exit the market, or accept state tort liability, Plaintiff's first, second, third, fourth, fifth, and sixth causes of action are due to be dismissed as preempted under *Mensing* and *Bartlett*.

B. *Buckman* Preemption

Defendants argue that Plaintiff's claims related to "off-label" promotion and the failure to provide a Medication Guide are impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and 21 U.S.C. § 337(a) because those claims are premised solely upon federal duties and there is no private right of action to enforce those federal duties.

The FDCA does not provide a private right of action for a defendant's violation of its provisions. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 810 (1986). Instead, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Accordingly, where "the existence of these federal

enactments is a critical element in [plaintiff's] case," and where a plaintiff's claims "exist solely by virtue of the FDCA ... requirements," state law claims are impliedly preempted by the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Where, by contrast, a plaintiff's claims rest on "traditional state tort law principles of the duty of care," the establishment of which "predated the federal enactments in question," a plaintiff may bring a state law claim for conduct also in violation of the FDCA. *Id*. *Buckman* does not extend so far as to restrict "certain state-law causes of actions that parallel federal safety requirements." *Id*.; *see Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1339 (10th Cir. 2015) ("*Buckman* left undisturbed ... state lawsuits based on 'traditional state tort law' that 'predate[s]' the FDCA but happens to 'parallel' it.").

Under *Buckman*, "[f]or a state-law claim to survive, ... the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Williams v. Smith & Nephew, Inc.*, 123 F.Supp.3d 733, 746 (D. Md. 2015) (quotations omitted); *see Evans v. Rich*, No. 5:13–CV–868–BO, 2014 WL 2535221, at *2 (E.D.N.C. June 5, 2014) ("The test for determining whether a state law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA."); *Loreto v. Procter & Gamble Co.*, 515 Fed.Appx. 576, 579 (6th Cir.2013) ("If the claim would not exist in the absence of the FDCA, it is impliedly preempted."); *see also In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir.2010) (recognizing "a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption[:] ... the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).") (quotations omitted).

Plaintiff does not address *Buckman* or its impact on Plaintiff's claims related to "off-label" promotion and the failure to provide a Medication Guide. He simply says *Mensing* does not apply. The Court views Plaintiff's failure to address Defendants' arguments regarding *Buckman* as telling.

Plaintiff's negligence claims based on the alleged "off-label" promotion of amiodarone are impliedly preempted under *Buckman* because the duties Plaintiff alleges Defendants breached regarding "off-label" promotion exist solely under the FDCA. Plaintiff has not directed the Court to any S.C. state law causes of action that parallel the federal safety requirements limiting the "off-label" promotion of drugs. Plaintiff's claim for "off-label" promotion of amiodarone would not exist in the absence of the FDCA. Accordingly, Plaintiff's claim for negligence and negligence per se based on Defendants' alleged "off-label" promotion of amiodarone for atrial fibrillation is impliedly preempted under *Buckman* and due to be dismissed. *See, e.g. Perdue v. Wyeth Pharms., Inc.*, __ F. Supp. 3d __, 2016 WL 3951091, at *5 (E.D.N.C. 2016) (dismissing plaintiff's claim for negligent "off-label" promotion of amiodarone because the claim was not premised on conduct that would give rise to a recovery under state law in the absence of the FDCA).

Plaintiff also asserts negligence claims based on Defendants' alleged failure to provide a Medication Guide with Bean's prescription of amiodarone as required by the FDA. The duty to provide a Medication Guide exists solely under the FDCA and its applicable regulations. *See* 21 U.S.C. § 355(j)(2)(A)(v) & 355(j)(4)(G))) and 21 C.F.R. § 208.24. Specifically, 21 C.F.R. § 208.24 provides that "[e]ach manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients." Because the requirement to provide a Medication Guide to distributors is based solely in the requirements of the FDCA and related regulations, and there is no parallel duty

to provide a Medication Guide under South Carolina law, Plaintiff's claims based upon failure to provide a Medication Guide are preempted under *Buckman*.[3] *See Perdue*, 2016 WL 3951091, at *5. In other words, Plaintiff's claims against Defendants for failure to provide a Medication Guide are preempted and due to be dismissed because the claims would not exist in the absence of the FDCA.

In summary, Plaintiff's third and fourth causes of action, which allege negligent "off-label" promotion and negligent failure to provide a Medication Guide, are preempted and due to be dismissed under *Buckman*.

II. Learned Intermediary Doctrine

Defendants argue that Plaintiff's Medication Guide claim fails under the learned intermediary doctrine because under South Carolina law, the drug manufacturer's duty to warn extends only to Bean's prescribing physician. Defendants further argue that Plaintiff's claims related to "off-label" promotion fail under the learned intermediary doctrine because Plaintiff has not alleged that Bean's prescribing physician was not adequately informed about the risks of amiodarone as a treatment for atrial fibrillation. Also telling is the fact that nowhere does Plaintiff respond to Defendants' learned intermediary doctrine arguments and, importantly, does not argue that the learned intermediary doctrine does not apply.[4]

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[3] It makes no difference that Plaintiff alleges the Medication Guides were not provided to distributors and pharmacists because the claims would not exist in the absence of the FDCA and there are no parallel duties to provide the Medication Guide under S.C. state law.

[4] Plaintiff's failure to respond to the learned intermediary argument is striking because Plaintiff's counsel has been involved in several other amiodarone cases that were dismissed in part pursuant to the learned intermediary doctrine. *See, e.g. Stephens v. Teva Pharms., U.S.A., Inc.*, 70 F. Supp. 3d 1246, 1254 (N.D. Ala. 2014); *Allain v. Wyeth Pharms., Inc.*, No. 2:14-cv-00280-KOB, 2015 WL 178038, at *6 (N.D. Ala. Jan. 14, 2015); *Connolly v. Sandoz Pharms. Corp.*, No. 2:14-cv-152-WCO, 2014 WL 12480025, at *5 (N.D. Ga. Dec. 23, 2014).

Although there is no South Carolina Supreme Court case specifically adopting the learned intermediary doctrine in the context of pharmaceutical drug or device litigation, the Fourth Circuit Court of Appeals has predicted that the South Carolina Supreme Court would adopt the doctrine if presented with the issue. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir.1992). Under the learned intermediary doctrine, "the manufacturer's duty to warn extends *only* to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." *Odom*, 979 F.2d at 1003 (emphasis added). The manufacturer of a drug has a duty to warn the patient's doctor who acts as a "learned intermediary" between the patient and the manufacturer. The rationale behind this doctrine is the doctor is in a better position to warn the patient than the manufacturer. In a prescription drug case, a plaintiff must not only show that the drug manufacturer's warning was inadequate, but "also establish that the inadequacy of the warning was the proximate cause of the plaintiff's injury." *Sauls*, 846 F. Supp. 2d at 502 (citing *Stanback v. Parke, Davis, & Co.*, 657 F.2d 642, 645 (4th Cir.1981)). In light of the learned intermediary doctrine, "the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Odom*, 979 F.2d at 1003.

Plaintiff's Medication Guide claims are due to be dismissed because, pursuant to the learned intermediary doctrine, the manufacturer's duty to warn only extends to the prescribing physicians, not the patient. *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir.1992); *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 504 (D.S.C. 2012); *Dreher v. Wyeth Pharms, Inc.*, No. 2:14-cv-00280-KOB, 2015 WL 3948961, at *8 (N.D. Ala. June 29, 2015).

As to Plaintiff's "off-label" promotion claims, Plaintiff's complaint fails to allege that Bean's prescribing physician would have changed his prescribing decision had different or additional warnings accompanied amiodarone. Plaintiff does not allege that the prescribing physician did not receive the Medication Guide, was unaware of its contents, or the risk of pulmonary toxicity or lung problems possibly resulting in death. Plaintiff, in fact, alleges that the warnings contained in the Medication Guide were adequate and sufficient to warn Plaintiff of the dangers and risks of taking amiodarone. Plaintiff has not alleged that the prescribing physician would have changed his decision to prescribe amiodarone had he been aware of the risk of pulmonary toxicity or lung problems possibly resulting in death, a risk that, according to Plaintiff, is adequately disclosed in the Medication Guide. Plaintiff has failed to state a claim to relief that is plausible on its face as Plaintiff has not pled facts sufficient to establish causation in light of the learned intermediary doctrine. *See, e.g. Luberda ex rel. Luberda v. Purdue Frederick Corp.*, No. 4:13-cv-00897-RBH, 2014 WL 1315558, at *6 (D.S.C. March 28, 2014). Plaintiff's failure to plead sufficient facts to overcome the learned intermediary doctrine is of no consequence here, where Plaintiff's claims are also preempted by federal law.

III. Request for Leave to Amend

Within his response to the motions to dismiss, Plaintiff requests leave to amend his complaint. A plaintiff may amend his complaint one time as a matter of course before the defendant files a responsive pleading. Fed.R.Civ.P. 15(a). Once the defendant files a responsive pleading, however, the plaintiff may amend his complaint only by leave of the court or by written consent of the defendant, however, Rule 15(a)(2) directs that leave to amend "shall be freely given when justice so requires." Leave to amend a pleading should be denied only when the amendment would

be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile. *See Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th Cir. 1986). In this case, Plaintiff does not elaborate as to what amendments he would make to his complaint but instead generally requests leave to amend in his memorandum in response to the motions to dismiss. Leave to amend is properly denied where the requested leave to amend is not accompanied by a motion to amend or a proposed amended complaint. *See Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 630-31 (4th Cir. 2008) (finding no abuse of discretion where plaintiffs requested leave to amend in a response but did not file a motion to amend or a proposed amended complaint). Furthermore, as discussed above, each of Plaintiff's claims is preempted by federal law under either *Mensing, Bartlett*, or *Buckman*. Any proposed amendment to the complaint would most likely be futile. For those reasons, Plaintiff's request for leave to amend is denied.

Conclusion

For the reasons stated above, Defendant Upsher-Smith Pharmaceuticals, Inc.'s [ECF No. 19] motion to dismiss is **GRANTED** and Taro Pharmaceuticals USA, Inc.'s [ECF No. 22] motion to dismiss is **GRANTED**. Plaintiff's motion to amend the complaint is **DENIED**. This case is hereby **DISMISSED**.

IT IS SO ORDERED.

September 29, 2017
Florence, South Carolina

s/ R. Bryan Harwell
R. Bryan Harwell
United States District Judge